

DEPARTMENT OF HEALTH & HUMAN SERVICES

August 18, 2000

## Certified/Return Receipt Requested

WARNING LETTER KAN #2000-023

Peter Y. Chun, President Chunco Foods, Inc. 1400 East 2<sup>nd</sup> Street Kansas City, MO 64106

Dear Mr. Chun:

Public Health Service

Food and Drug Administration Kansas City District Office 11630 West 80th Street P.O. Box 15905 Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

Our investigator conducted an inspection of your manufacturing facility, located at the above address, between July 12-24, 2000. This inspection disclosed practices at your facility that concern us and that cause your sprouts to be in violation of the Federal Food, Drug, and Cosmetic Act (the Act).

Specifically, our inspection revealed that your sprouts are adulterated within the meaning of Section 402(a)(4) of the Act because they have been prepared, packed or held under insanitary conditions whereby they may have been contaminated with filth or whereby they may have been rendered injurious to health. The conditions under which the sprouts are being produced are considered insanitary since effective preventive controls, particularly microbial testing of spent irrigation water, have not been implemented at your facility.

The following is a list of insanitary practices, conditions, and findings observed by our investigator during this inspection:

No microbial testing of spent irrigation water used in sprouting.

Poor storage practices which include equipment stored on top of bagged mung beans; flats of sprouts stored directly on top of each other; rusted equipment used for storing sprouts on; uncovered mung beans in finished product cooler.

Equipment used in sprouting process is not kept clean. Examples include excessive buildup of debris on the sprout spin dryer; interior of sprout chamber doors has buildup of grease and dirt; beams and automatic water spreader above sprouting chambers are rusty and crusted with debris; water hoses used in sprouting are lying on the floor; sprout buckets stored on the floor; sprout transport tubs are dirty and have duct tape on them.

Poor facility maintenance in the production areas which include exposed electrical wires and insulation; no protective shields on light fixtures; deteriorating ceilings and walls; condensation noted on ceilings above food products; no back flow prevention devices on water hoses.

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Poor employee practices which include personal items such as shoes and keys, and food and drink observed in production areas; employees not washing their hands or using gloves after returning to alfalfa growing/packing room; no hair restraints being used in production areas.

This is not intended to be an all-inclusive list of deviations at your facility. It is your responsibility to ensure compliance with all applicable laws and regulations.

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. This may include seizure and/or injunction. During the inspection, our investigator provided you with copies of two guidance documents intended to assist the sprout industry in producing safe products, "Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production," and "Reducing Microbial Food Safety Hazards for Sprouted Seeds." To address our concerns, you could follow the guidance provided in these documents or establish an alternative approach that satisfies the requirements of the Act and regulations.

You should notify this office in writing within fifteen (15) working days from the date you received this letter, of the steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

District Director

Kansas City District